



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,261	01/23/2004	Edward P. Perez	7404-612	6175

7590 11/17/2004

Woodard, Emhardt, Moriarty, McNett & Henry LLP
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
----------	--------------

3736

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/764,261	Applicant(s) PEREZ ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>06212004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. This application repeats a substantial portion of prior Application Nos. 09/586,969, filed 05 June 2000; 09/238,140, filed 28 January 1999; and 08/858,043, filed 16 May 1997, and adds and claims additional disclosure not presented in the prior applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior applications, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

2. Applicant has declared that this application is a continuation-in-part of prior Application No. 09/542,040, filed 31 March 2000. Application No. 09/542,040 is a continuation of prior Application No. 09/285,021, filed 01 April 1999, which is a continuation of prior Application No. 08/975,978, filed 21 November 1997. No claim for domestic priority has been made for the parent applications of prior Application No. 09/542,040. Should applicant desire to obtain the benefit of the filing date of the prior applications, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Specification

3. The disclosure is objected to because of the following informalities:
- a. On page 1, lines 8-9, the current status of the parent application also should be provided.

Art Unit: 3736

- b. On page 18, line 9, “trigger 46” apparently should read --trigger 49--.

Appropriate correction is required.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

5. Claim 1 is objected to because of the following informalities: in line 3, “deice” apparently should read --device--. Appropriate correction is required.
6. Claim 7 is objected to because of the following informalities: in line 2, “user’s body” apparently should read --body of the user--. Appropriate correction is required.
7. Claim 9 is objected to because of the following informalities: in line 4, “remove” apparently should read --removing--. Appropriate correction is required.
8. Claim 17 is objected to because of the following informalities: in line 2, “a” apparently should be deleted. Appropriate correction is required.
9. Claim 19 is objected to because of the following informalities: in line 3, --and-- apparently should be inserted following “member,”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 3, 5, 6 and 9-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the bulged incision" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no bulged incision recited in the claims prior to this recitation.

Claim 5 and 6 recite the limitation "the region of the incision" in line 2. There is insufficient antecedent basis for this limitation in the claims. There is no region of the incision recited in the claims prior to these recitations.

Regarding claim 9, the limitation "a longitudinal axis of the housing the axis and" in lines 11-12 is unclear and ambiguous.

Claim 10 recites the limitation "the end surface" in line 13. There is insufficient antecedent basis for this limitation in the claim. There is no end surface recited in the claim prior to this recitation. This limitation also occurs in line 1 of claim 10.

Regarding claim 16, the pronoun its renders the claim indefinite. One cannot be certain what its is referring to.

Regarding claim 20, it is unclear whether only one leg has a biasing member or if each of the at least one legs has a biasing member.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange et al. Lange et al. teach a method for obtaining a sample of body fluid from an ear lobe. The method includes the steps of providing a skin lancing medium contained within a housing and driving the skin-lancing mechanism out an open end of the housing against the ear lobe to form an incision in the skin; retracting the skin lancing mechanism; and applying an open end of the housing to the skin surface thereby depressing the skin in a manner to form a depressed ring of body tissue in surrounding relationship to the incision. Lange et al. teach all the limitations of the claims except for an explicit recitation of the specific method steps of the instant invention. It would have been obvious to one skilled in the art at the time the invention was that the steps of the instant method would inherently be required to use the apparatus of Lange et al. in order to obtain a body fluid sample from an incision.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*,

Art Unit: 3736

422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 and 25-31 of U.S. Patent No. 6,706,000. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application either use different language to claim an equivalent apparatus as that claimed in the patent or are merely broader than the claims of the patent.

Independent claim 1 of the present application recites a method that is merely broader than that claimed in independent claim 25 of the patent. Claim 25 of the patent recites all of the method steps of claim 1 of the present application, plus an additional wherein clause that is recited in claim 4 of the present application. Claims 2, 3 and 5-8 of the present application are substantially equivalent to claims 26-31 of the patent, respectively. Since the broader claims of the present application are “anticipated” by the narrower claims of the patent, the claims are not patentably distinct.

Independent claim 9 of the present application recites a device that is structurally equivalent to the device recited in claim 1 of the patent, the claims differing only in certain aspects of the claim language. Claims 10-13 and 14-16 of the present application are substantially equivalent to claims 2-5 and 7-9 of the patent, respectively. Claim 17 of

Art Unit: 3736

the present application is substantially equivalent to claim 6 of the patent. Claims 18-20 of the present application are substantially equivalent to claims 10-12 of the patent, respectively. Since the aforementioned claims of the present application claim a device that is structurally equivalent to the aforementioned apparatus claims of the patent, the claims are not patentably distinct.

16. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,951,493. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one skilled in the art at the time the invention was made to perform the method steps A-C of claim 1 of U.S. Patent No. 5,951,493 while omitting steps D and E. This effectively would amount to applying pressure to the incision only one time, as claimed by the present application, rather than repeatedly as claimed by U.S. Patent No. 5,951,493. Claims 3-8 of the instant application correspond to claims 2-7 of the patent, respectively. Since the more specific claims of the patent “anticipate” the broader claims of the instant application, the claims are not patentably distinct.

17. Claims 1-4 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,071,250. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of U.S. Patent No. 6,071,250. The method, as claimed in the instant application, effectively

Art Unit: 3736

would amount to applying pressure to the incision only one time, rather than repeatedly as claimed by U.S. Patent No. 6,071,250. Since the more specific claims of the patent “anticipate” the broader claims of the instant application, the claims are not patentably distinct.

18. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,319,210. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the instant application would inherently be required as a method of using the device of U.S. Patent No. 6,319,210. The apparatus of claim 1 of U.S. Patent No. 6,319,210 recites all of the structural limitations claimed in the providing steps of the method of claim 1 in the instant application. It would have been obvious to one having ordinary skill in the art at the time Applicant’s invention was made that, in order to use the device of U.S. Patent No. 6,319,210, the lancing device would have to be applied to the skin to form an incision, the lancing device would have to be removed from the incision; and a force would have to be applied with the stimulating member to depress a ring of body tissue surrounding the incision to express body fluid from the incision.

19. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 5,964,718. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the instant application would inherently be required as

Art Unit: 3736

a method of using the device of U.S. Patent No. 5,964,718. The apparatus of claim 18 of U.S. Patent No. 5,964,718 recites all of the structural limitations claimed in the providing steps of the method of claim 1 in the instant application. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that, in order to use the device of U.S. Patent No. 5,964,718, the lancing device would have to be applied to the skin to form an incision, the lancing device would have to be removed from the incision; and a force would have to be applied with the stimulating member to depress a ring of body tissue surrounding the incision to express body fluid from the incision.

20. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 of U.S. Patent No. 6,066,103. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the instant application would inherently be required as a method of using the device of U.S. Patent No. 6,066,103. The apparatus of claim 21 of U.S. Patent No. 6,066,103 recites all of the structural limitations claimed in the providing steps of the method of claim 1 in the instant application. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that, in order to use the device of U.S. Patent No. 6,066,103, the lancing device would have to be applied to the skin to form an incision, the lancing device would have to be removed from the incision; and a force would have to be applied with the stimulating member to depress a ring of body tissue surrounding the incision to express body fluid from the incision.

21. Claims 1-4 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,183,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of U.S. Patent No. 6,183,489. The method, as claimed in the instant application, effectively would amount to applying pressure to the incision only one time, rather than repeatedly as claimed by U.S. Patent No. 6,183,489. Since the more specific claims of the patent “anticipate” the broader claims of the instant application, the claims are not patentably distinct.

22. Claims 9-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-15, 17, 18 and 20 of U.S. Patent No. 5,951,493 in view of Shain et al. Claim 1 of U.S. Patent No. 5,951,493 teach all of the limitations of claim 9 of the instant application except that the device includes a constricting member mounted to the open end of the housing. Claims 9-15, 17, 18 and 20 of U.S. Patent No. 5,951,493 correspond to claims 10-19 of the instant application, respectively. Shain et al. teach that it is advantageous to provide a lancing device with a mechanism for pinching (constricting) the skin in combination with a stimulating member in order to increase the volume of blood extracted from the incision (col. 7, line 66 - col. 8, line 18). It would have been obvious to one skilled in the art at the time Applicant’s invention was made to provide a device similar to that of claims 8 of U.S.

Art Unit: 3736

Patent No. 5,951,493 with a constricting member in view of the teachings of Shain et al. in order to increase the volume of blood extracted from the incision.

23. Claims 9-11 and 13-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5-9 and 11 of U.S. Patent No. 6,071,250 in view of Shain et al. The aforementioned claims of U.S. Patent No. 6,071,250 teach all of the limitations of claims 9-11 and 13-19 of the instant application except that the device includes a constricting member mounted to the open end of the housing. Shain et al. teach that it is advantageous to provide a lancing device with a mechanism for pinching (constricting) the skin in combination with a stimulating member in order to increase the volume of blood extracted from the incision (col. 7, line 66 - col. 8, line 18). It would have been obvious to one skilled in the art at the time Applicant's invention was made to provide a device similar to that of U.S. Patent No. 6,071,250 with a constricting member in view of the teachings of Shain et al. in order to increase the volume of blood extracted from the incision.

24. Claims 9-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,319,210 in view of Shain et al. Claim 1 of U.S. Patent No. 6,319,210 teach all of the limitations of claims 9-11 of the instant application except that the device includes a constricting member mounted to the open end of the housing. Shain et al. teach that it is advantageous to provide a lancing device with a mechanism for pinching (constricting) the skin in combination with a stimulating member in order to increase the volume of blood

Art Unit: 3736

extracted from the incision (col. 7, line 66 - col. 8, line 18). It would have been obvious to one skilled in the art at the time Applicant's invention was made to provide a device similar to that of claim 1 of U.S. Patent No. 6,319,210 with a constricting member in view of the teachings of Shain et al. in order to increase the volume of blood extracted from the incision.

25. Claims 9-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 5,964,718 in view of Shain et al. Claim 18 of U.S. Patent No. 5,964,718 teach all of the limitations of claims 9-11 of the instant application except that the device includes a constricting member mounted to the open end of the housing. Shain et al. teach that it is advantageous to provide a lancing device with a mechanism for pinching (constricting) the skin in combination with a stimulating member in order to increase the volume of blood extracted from the incision (col. 7, line 66 - col. 8, line 18). It would have been obvious to one skilled in the art at the time Applicant's invention was made to provide a device similar to that of claim 18 of U.S. Patent No. 5,964,718 with a constricting member in view of the teachings of Shain et al. in order to increase the volume of blood extracted from the incision.

26. Claims 9-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 22 of U.S. Patent No. 6,066,103 in view of Shain et al. Claim 22 of U.S. Patent No. 6,066,103 teach all of the limitations of claims 9-11 of the instant application except that the device includes a constricting

Art Unit: 3736

member mounted to the open end of the housing. Shain et al. teach that it is advantageous to provide a lancing device with a mechanism for pinching (constricting) the skin in combination with a stimulating member in order to increase the volume of blood extracted from the incision (col. 7, line 66 - col. 8, line 18). It would have been obvious to one skilled in the art at the time Applicant's invention was made to provide a device similar to that of claim 22 of U.S. Patent No. 6,066,103 with a constricting member in view of the teachings of Shain et al. in order to increase the volume of blood extracted from the incision.

27. Claims 9-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,183,489 in view of Shain et al. Claim 1 of U.S. Patent No. 6,183,489 teach all of the limitations of claims 9-11 of the instant application except that the device includes a constricting member mounted to the open end of the housing. Shain et al. teach that it is advantageous to provide a lancing device with a mechanism for pinching (constricting) the skin in combination with a stimulating member in order to increase the volume of blood extracted from the incision (col. 7, line 66 - col. 8, line 18). It would have been obvious to one skilled in the art at the time Applicant's invention was made to provide a device similar to that of claim 1 of U.S. Patent No. 6,183,489 with a constricting member in view of the teachings of Shain et al. in order to increase the volume of blood extracted from the incision.

Art Unit: 3736

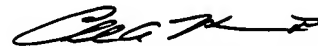
Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
November 9, 2004